

high TB group is lower than that of low TB group (14.9% vs. 29.0% for all cause death, $P=0.038$; 9.5% vs. 27.5% for cardiac death, $p=0.006$). In a multivariate Cox regression analysis, after adjusted for age, left ventricular ejection fraction (LVEF) et al., the patients had the lower incidence of all cause death and cardiac death in the high TB group than that in the low TB group (OR:0.423, 95%CI 0.184-0.975, $p=0.043$, vs. OR: 0.281, 95%CI 0.103-0.765, $P=0.013$, respectively).

Conclusions: Serum high TB level on admission is a protective and independent predictor of long term outcomes among no-reflow patients with STEMI undergoing primary PCI. In addition, TB concentrations may be a novel candidate biomarker for stratification of risk in no reflow patients with STEMI during primary PCI.

Antiplatelet Therapy

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Universal Ticagrelor Versus Assay-Driven Antiplatelet Therapy in Acute Coronary Syndrome Patients: A Cost-Effectiveness Analysis

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Background: Assays have been developed to monitor on-P2Y12 platelet reactivity, and these tests can accurately predict which patients will have poor response to clopidogrel. We sought to determine the cost-effectiveness of using a platelet reactivity assay to aid in the selection between ticagrelor and clopidogrel based dual antiplatelet therapy in ACS patients.

Methods: A hybrid decision tree/Markov model was used to calculate 5 year costs (2011 US\$), quality adjusted life years (QALYs) and incremental cost-effectiveness ratios (ICERs) of 1 year of platelet reactivity assay-driven ticagrelor (given to patients with high platelet reactivity defined as >230 on the VerifyNow P2Y12 assay, Accumetrics, San Diego, CA, others got generic clopidogrel) or universal (given to all patients) ticagrelor. We assumed a cohort of 65 year old ACS patients and 32% and 13% incidences of high platelet reactivity at discharge and at 1 month. The analysis was conducted from a US payer perspective and used a 1 year cycle length. Data depicting the efficacy and safety of ticagrelor and clopidogrel were taken from multinational randomized trials.

Results: Patients experiencing an acute coronary event treated with ticagrelor or clopidogrel based upon the results of the platelet reactivity assay lived an average of 3.497 QALYs at a treatment cost of \$30,615. Those receiving universal ticagrelor lived an average of 3.530 QALYs and incurred costs of \$32,865 (ICER for universal ticagrelor = \$68,182/QALY). Universal ticagrelor was not cost-effective unless the yearly cost of ticagrelor was $< \$2,800$, the yearly cost of clopidogrel rose above \$1,100 or the hazard ratio for death on ticagrelor vs. clopidogrel was < 0.74 . Monte Carlo simulation suggested universal and platelet reactivity assay-driven selection of ticagrelor would have ICERs $< \$50,000/QALY$ (be cost-effective) in 26% and 74% of 10,000 iterations, respectively.

Conclusion: Universal ticagrelor was not cost-effective compared to platelet reactivity assay-driven use of ticagrelor or clopidogrel. In the age of generic clopidogrel, assay-driven selection of antiplatelet therapy appears to be a reasonable strategy to decrease ACS associated healthcare costs.

CRT-33

Peri-procedural CK-MB Levels In Percutaneous Coronary Intervention With High-dose Bolus Tirofiban Vs. Abciximab Plus Either Unfractionated Heparin Or Bivalirudin: An Analysis From TENACITY

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Background: TENACITY was a randomized 2×2 factorial trial comparing high-dose bolus (HDB) tirofiban vs. abciximab, and unfractionated heparin (UFH) vs. bivalirudin, in patients undergoing percutaneous coronary intervention (PCI). The primary endpoint

of 30-day death, myocardial infarction, or urgent target vessel revascularization occurred in 6.9% and 8.8% of patients randomized to HDB tirofiban and abciximab, respectively. In this analysis, we retrospectively analyzed CK-MB levels in the 4 arms of the study.

Methods: Serial CK-MB samples were obtained in 380 of the 383 enrolled patients.

Results: A non-inferiority analysis with margin of 2 ng/mL was performed using PROC TTEST of SAS version 9.2, with HDB tirofiban and abciximab study arms pooled across levels of UFH and bivalirudin. The non-inferiority of HDB tirofiban vs. abciximab was established from a one-sided test for the difference in peak CK-MB means (p -value = 0.011), with a corresponding 90% confidence interval of (-0.52, 6.86) for abciximab minus HDB tirofiban.

Variable Analyzed	HDB Tirofiban + AT (n=189) (ng/mL)	Abciximab + AT (n=191) (ng/mL)	UFH + GPI (n=195) (ng/mL)	Bivalirudin + GPI (n=185) (ng/mL)
Median Peak CK-MB	2.6	2.6	2.7	2.5
Peak CK-MB Percentile 25-75	1.6-6.4	1.3-5.5	1.3-6.4	1.4-5.6
Median CK-MB from serial draw #1	1.5	1.5	1.6	1.4
Median CK-MB from serial draw #2	1.8	1.8	1.8	1.8
Median CK-MB from serial draw #3	2.1	2.2	2.2	2.1
Median CK-MB from serial draw #4	2.2	2.3	2.3	2.3
Median CK-MB from serial draw #5	2.5	3.1	3.5	2.3

AT=UFH or bivalirudin; GPI=tirofiban or abciximab.

Conclusions: CK-MB levels are similar after the administration of HDB tirofiban and abciximab, and UFH and bivalirudin, in this prematurely terminated, undersized trial. These data do suggest, however, that HDB tirofiban and abciximab, and UFH and bivalirudin, may be similar in their ability to prevent peri-procedural myocardial infarction in moderate to high-risk patients undergoing PCI. These data should be useful in identifying the size of an appropriately powered trial necessary to compare these regimens.

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Outcomes Of Anti-platelet Therapy For Acute Coronary Syndromes Patients Directed By Post Pci Platelet Function Testing In A Real World Setting

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Objectives: To assess whether Accumetrix VerifyNow P2Y12 testing directed anti-platelet therapy after acute coronary syndromes (ACS) percutaneous coronary intervention (PCI) in a real world setting, could affect outcomes.

Background: Multiple trials suggest that high residual on-treatment platelet reactivity (HRPR) [Platelet Reactivity Units (PRU) ≥ 230] increases the incidence of major adverse cardiac events: death, myocardial infarction, target vessel revascularization and stent thrombosis (MACE). Data on routine real world testing of ACS patients is lacking.

Methods: 371 ACS patients had PCI and platelet function testing after initial background aspirin and ≥ 600 mg of clopidogrel. For PRU at 12-24 hours < 230 , maintenance 325 mg/day of aspirin and 75 or 150 mg/day of clopidogrel for 1 week then 75 mg/day were continued unless followup testing at 1-3 weeks demonstrated HRPR. Most patients with initial HRPR were switched to prasugrel or ticagrelor with no further testing, as hyporesponse is rare; or clopidogrel 150 mg/day with repeat testing at 1-3 weeks. Continued HRPR on clopidogrel usually drove switching to prasugrel or ticagrelor unless contraindicated.

Results: There were 148 (40%) HRPR and 223 (60%) responders patients. MACE was similar between the two groups [5/148 (3.4%) vs. 6/223 (2.7%), respectively, $p=0.76$]. Even after subdividing ACS to unstable angina (UA) and Non ST elevation MI

(NSTEMI) vs. ST elevation MI (STEMI) MACE was similar for HRPR and responders [4/113 (3.5%) vs. 6/163 (3.7%), respectively, $p=NS$, for UA/NSTEMI and 1/35 (2.8%) vs. 2/60 (3.3%), respectively, $p=NS$, for STEMI]. The 30 day incidence of stent thrombosis was only 1 in the HRPR group and was related to medication noncompliance.

Conclusions: Adjusting anti-platelet therapy for ACS patients on the basis of Veri-fyNow testing results in low and equivalent MACE at 30 days after PCI, for initial anti-platelet responders and HRPR patients switched to more effective therapy.

Atherectomy Devices

CRT-35

Rotational Atherectomy Prior To And During The Drug-eluting Stent Era: Procedural Outcomes And Clinical Follow-up Results

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Background: In recent years, several modifications in rotational atherectomy technique have been developed. However, no study has evaluated the clinical outcomes of rotational atherectomy prior to- and during the DES era.

Methods: All patients who underwent rotational atherectomy for complex coronary lesions in our center prior to- and during the current DES era were retrospectively enrolled. Baseline clinical and angiographic characteristics were compared; as were procedural success and clinical outcomes at 1 year.

Results: Among the 215 patients included in the analysis, 74 (22%) were from the pre-DES era while 141 (78%) were from the DES era. More patients in the DES era group had history of peripheral vascular disease and hypertension (25% vs. 15.4%, $p=0.04$) and (96% vs. 77.5%, $p<0.001$), retrospectively. Procedural success was higher in DES era group (99.6% vs. 93.6%, $p<0.001$); furthermore the DES era group was associated with a lower in-hospital coronary artery bypass surgery (0.5% vs. 4%, $p=0.03$), dissection rate (0.0% vs. 2.3%, $p=0.04$), abrupt closure (0.0% vs. 3.8%, $p=0.006$). One-year follow up showed a lower rate of death in the DES era group (5.0% vs. 14.6%, $p=0.04$).

Conclusion: In the DES era, rotational atherectomy has become safer and effective procedure for complex coronary lesions.

Variable	DES Era(n=141)	Pre-DES Era(n=74)	p Value
6 months follow-up			
TVR MACE	14 (9.5%)	7 (11.1%)	0.72
TLR MACE	13 (8.8%)	7 (11.1%)	0.60
Death	6 (4.1%)	6 (9.5%)	0.19
TLR	7 (4.9%)	1 (1.6%)	0.44
TVR	8 (5.6%)	1 (1.6%)	0.28
QWMI	0	0	0.00
NQWMI	3 (2.2%)	0	0.57
ST	0	0	0.00
1 year follow-up			
TVR MACE	21 (15%)	12 (25%)	0.11
TLR MACE	20 (14%)	12 (25%)	0.08
Death	7 (5%)	7 (14.5%)	0.04
TLR	13 (9.6%)	5 (11%)	0.77
TVR	14 (10.4%)	5 (11%)	1.00
QWMI	0	0	0.00
NQWMI	3 (2.2%)	0	0.57
ST	0	0	0.00

TVR= target vessel revascularization; MACE= major adverse cardiovascular event; TLR= target lesion revascularization; QWMI= Q-wave myocardial infarction; NQWMI= non Q-wave myocardial infarction; ST= stent thrombosis; Max= maximum.

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Plaque Modification Versus Debulking Strategy In Calcified Coronary Lesions. Long-term Clinical Outcome And Technical Determinants Of The Rotational Atherectomy (the Rotablator Udine Registry)

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Introduction: Percutaneous coronary intervention (PCI) of heavily calcified lesions is a challenge for the interventional cardiologist. The aim of this study was to investigate the immediate and long-term outcome of patients (pts) treated with rotational atherectomy (RA).

Methods: All consecutive pts treated by PCI with RA at our center between 09/1998-12/2011 entered in a database and were analyzed retrospectively. Clinical indication were Acute Coronary Syndrome in 148 pts (52%). Data of early and late (mean follow-up 69 ± 52 months) major adverse cardiac events (MACE) included cardiac death, stroke, acute myocardial infarction (AMI) and target lesion failure (TLF).

Results: A total of 283 pts (306 lesions) were included. Mean age was 70 ± 10 , 80% were male, 33% diabetic and 42% had chronic renal failure (CRF). 234 pts (83%) had multivessel disease. According to ACC/AHA classification, 79% were type C. Mean vessel diameter was 3.3 ± 0.4 mm. After RA, cutting-balloon (CB) was used in 35% of cases. Drug eluting stents (DES) were implanted in 44% of pts, bare metal (BMS) in 47%. Pts were divided in two groups, according to Burr/Artery Ratio (BAR): group 1 ($BAR\leq 0.5$ plus cutting-balloon use, 64%) and group 2 ($BAR>0.5$ with or without cutting-balloon, 31%). Procedural success was 96.6%, early mortality 1.4%, stroke or TIA 1.4%, acute renal injury 5.3%. CK-MB rise $> 5x$ Upper Limit value occurred in 2.8% of pts and vessel perforation in 1.4%. CRF (95% CI, 1.2-1.7, $p=0.03$), Peripheral Artery Disease (CI 95% 1.6-6.6, $p=0.006$), no use of cutting-balloon in lesion treated with $BAR\leq 0.5$ (CI 95% 1.2-42.3, $p=0.0001$) and transient/persistent slow-no flow (CI 95% 1.5-9.8, $p=0.01$) were independent predictor of MACEs. Persistent no-slow flow occurred